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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/848,737	05/19/2004	Hsiang-Fu Kung	V9661.0080	7269

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EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/848,737	KUNG ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2005, 12/8/2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-14 and 20-33* is/are pending in the application.

4a) Of the above claim(s) *5,6,10,12 and 14* is/are withdrawn from consideration.

5)☒ Claim(s) *33* is/are allowed.

6)☒ Claim(s) *1-10 12-14 20-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 5, 6, 10, 12, 14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 7, 2005. Although SEQ ID NO:4 was non-elected in the first action, in this instance it will be examined together with SEQ ID NO:1 because it does not impose an undue burden.

Claim construction

MPEP 2111.03 states:

> The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).... For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.); In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

It is noted that the specification discusses one method of use (RNA interference), where addition of substantial additional nucleotides would materially alter the basic properties of the invention. However, both the specification and the recent response discuss an alternative method of use, (producing immunogenic polypeptides) where addition of substantial additional nucleotides would not materially alter the basic properties of the invention. The specification does not have a definition of "consisting essentially of;" applicant relies at least in part on the method of use for producing immunogenic polypeptides; and there is no clear indication in the specification or claims of what the basic and novel characteristics actually are for the immunogenic-peptide encoding nucleic acids. Therefore, "consisting essentially of" will be construed as equivalent to "comprising."

Claim Rejections - 35 USC § 102

Claims 1-4, 7-9, 13, 20-31 are rejected under 35 U.S.C. 102(e) as being anticipated by McSwiggen et al WO 2004/092383, for the same reasons as discussed in the previous Office action. Also see McSwiggen seq 66 (page 147, starting with "1191") for a nucleic acid with at least 10 nucleotides of applicant's Seq 4. Applicant argues that McSwiggen teaches a large number of sequences that "could be siRNAs with possible efficacies," and does not disclose which sequences are actually effective. However, these claims are drawn to compounds and compositions, and the reference teaches the compounds and compositions that meet each and every claim limitation. The fact that the reference teaches a multitude of other compounds does not negate the prior teaching of the claimed compounds.

Claims 1 and 4, 20 and 23 are remain rejected under 35 U.S.C. 102(e) as being anticipated by Fodor et al, for the same reasons as discussed in the previous Office action. Applicant argues that Fodor discloses all possible 10-mers but does not teach or suggest any specific sequences of the claimed invention. Since these claims are drawn, at least in part, to 10-mers, they are necessarily within the scope of "all possible 10-mers" and are therefore taught by the reference.

Claims 1-4, 20-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank locus AY274119, version AY27419.1 or GI:29826276, for the same reasons as discussed in the previous Office action. Because of the claim construction discussed above, the prior art sequence still meets the limitations of claims 1-3 and 20-22. In addition, the prior art sequence would clearly meet the limitations of claims 4 and 23, since the full genome would hybridize to a sequence consisting of SEQ 1 or 4 or a complement thereof, under "stringent" conditions that permit 30% sequence mismatch (as "stringent" is defined by the specification).

Claim Rejections - 35 USC § 112

Claims 13, 27, 28, 30-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic formulations, does not reasonably provide enablement for pharmaceuticals or methods of preventing or treating SARS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Prentice et al (Journal of Virology 78:9911-9986, 2004, not prior art) is cited as providing evidence substantiating assertions in the

specification that antibodies made to the products encoded by the claimed nucleic acids can be used for virus detection, see for example figures 3 and 4. Therefore this rejection is not directed to claims 9, 26, and 29. Applicant argues that showing efficacy of the formulation or composition is not required to meet enablement requirements. However, when the claim is directed to a pharmaceutical composition or to a treatment method, the specification must enable pharmaceutical use and use in treatment. The therapeutic effect of an immune response is unpredictable, particularly for coronaviruses, which provide a classic example of immune enhancement of disease in feline infectious peritonitis virus. For non-immunogenic treatments (e.g. siRNA), the clinical usefulness of the method remains un-established, as previously discussed. Considering the unpredictability of a beneficial therapeutic response, the limited guidance provided in the specification, the undeveloped state of the art, and the absence of working examples, it is maintained that undue experimentation would be required to use the invention as claimed.

Allowable Subject Matter

Claim 33 is allowed. Claims directed to a nucleic acid consisting of SEQ ID NO: 4 (or a complement thereof) would also be allowable. Applicant has described an unexpected result in the superior inhibition of infection in cultured cells using SEQ ID NO:4, and that oligonucleotide is not identical to any oligonucleotide explicitly disclosed in the closest prior art (McSwiggen).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/6/06

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER